

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/DIK 480 SL

Product name(s): Macamba 480 SL, Dikambin 480 SL

Chemical active substance(s):

Dicamba, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

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Version history

When	What
01/2023	Dossier sent for evaluation
03/2023	Applicant update
04/2023	zRMS evaluation of dRR
06/2023	Final version prepared by zRMS after Commenting period

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zRMS comments:

This report has been completed by the Applicant.
The text highlighted in grey was provided by the zRMS.

7 Metabolism and residue data (KCA section 6)

In the following document, data for active substances - dicamba - was described during its inclusion on Annex 1 process in respectively 2009. Where reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I

7.1 Summary and zRMS Conclusion

zRMS comments:

Comparison of EU critical GAPs with the proposed use of CHR/H/DIK 480 SL on maize is presented below:

Source of GAP	Member State or Country	Formulation	Growth stage at application	Number of applications	Application rate per treatment (kg as/ha)	PHI
SANCO/829/08-final rev.2, 12 July 2016 EFSA Journal 2011;9(1):1965	EU (N&S)	SL	Post-emergence until BBCH 16	1	0.360	- Period between treatment and harvest is > 100 days, no PHI is applicable
Intended GAP	PL (N)	SL	12-16	1	0.288	-

The EU GAP covers GAP proposed for CHR/H/DIK 480 SL.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.5 mg/kg for maize as laid down in Reg. (EU) 396/2005 is not expected.

Considering dietary burden and based on the intended uses the modification of MRLs in commodities of animal origin is not necessary.

The chronic and the short-term intakes of dicamba residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use on maize.

According to available data, no specific mitigation measures should apply.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/DIK 480 SL are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for winter cereals. A list of all intended uses within the zone/EU is given in Part B, Section 0.

Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.5 mg/kg for maize as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of dicamba residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are:

- None

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8					9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Maize	N-EU	CHR/H/DIK 480 SL	F		SL	480	Spray	BBCH 12- 16	a)1 b)1	n/a	a) 0.6 L/ha b) 0.6 L/ha	200-300	a) 288 g as/ha b) 288 g as/ha	n/a	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation ~~CHR/H/PENDIF 599.5 SC~~ CHR/H/DIK 480 SL is composed of dicamba.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of dicamba

Reference value	Source	Year	Value	Study relied upon	Safety factor
Dicamba - Parent compound					
ADI	EFSA	2011	0.3 mg/kg bw/day	Rat, 2-generation study	100
ARfD	EFSA	2011	0.3 mg/kg bw/day	Rabbit, teratology study	100

7.1.2.1 Summary for dicamba

Table 7.1-3: Summary for dicamba

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Maize	Yes	Yes (n=9)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For maize, no additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: 1 application of 288 g/ha at growth stage BBCH 12-16.

As residues of dicamba do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Considering dietary burden and based on the intended uses, further investigation of residues as well as the modification of MRLs in commodities of animal origin is not necessary.

7.1.2.2 Summary for CHR/H/DIK 480 SL

Table 7.1-4: Information on CHR/H/DIK 480 SL (KCA 6.8)

Crop	PHI for CHR/H/DIK 480 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/H/DIK 480 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Dicamba		
Maize	NR	NR	Period between treatment and harvest is >100 days, no PHI is applicable	-

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for CHR/H/DIK 480 SL
Crop group	Led by dicamba	
Leafy vegetables	NR	NR
Root vegetables	NR	NR
Cereals	NR	NR
Pulses and Oilseed rape	NR	NR

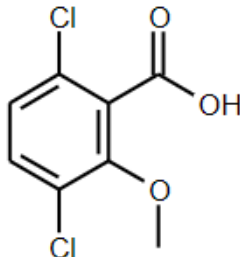
NR: not relevant

Assessment

7.2 Dicamba

General data on dicamba are summarized in the table below (last updated YYYY/MM/DD)

Table 7.2-1: General information on Dicamba

Active substance (ISO Common Name)	Dicamba
IUPAC	3,6-dichloro-2-methoxybenzoic acid
Chemical structure	
Molecular formula	C ₈ H ₆ Cl ₂ O ₃
Molar mass	221.0 g/mol
Chemical group	synthetic auxin herbicides". Benzoic acids
Mode of action (if available)	Auxin herbicides such as dicamba act as mimics of IAA at high concentrations.
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	DK
Approval status	COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substance
Restriction (e.g. is restricted to use as "...")	COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 Only uses as herbicide may be authorised.
Review Report	SANCO/829/08 – final rev. 2 12 July 2016

Current MRL regulation	Reg. (EU) 2015/845
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	EFSA Journal 2011;9(1):1965
EFSA Journal: conclusion on article 12	No**
Current MRL applications on intended uses	Reg. (EU) 2015/845 None

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize grain	High starch content	36 months for dicamba and 5-OH-dicamba	EFSA Journal 2011;9(1):1965
Maize forage, silage and fodder	High water content	36 months for dicamba and 5-OH-dicamba	36 months for dicamba and 5-OH-dicamba
Animal Products			
Ruminant	Liver	18 months	EFSA Journal 2011;9(1):1965
Ruminant	Kidney	18 months	EFSA Journal 2011;9(1):1965
Ruminant	Fat	18 months	EFSA Journal 2011;9(1):1965
Ruminant	Muscle	18 months	EFSA Journal 2011;9(1):1965
Ruminant	Milk	18 months	EFSA Journal 2011;9(1):1965

Conclusion on stability of residues during storage

The storage stability of dicamba and 5-OH-dicamba has been investigated in corn forage, grain, silage and fodder. The studies showed that residues of dicamba and 5-OH dicamba was stable in corn forage, grain and fodder for up to three years at -17°C and in corn silage for up to 24 months.

The storage stability of dicamba and DCSA has also been investigated in beef liver, kidney, muscle, fat and milk and the results showed that dicamba and DCSA were stable in beef kidney, liver, muscle, fat and milk for up to 18 months.

zRMS comments:

The stability of residues for dicamba and 5-OH-dicamba was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies and they are not required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in DAR Dicamba – Volume 3, Annex B, part 3, B.7, analysis time were less than 24 hours between extraction and analysis

zRMS comments:

The stability of residues in sample extracts is not required. All samples were analyzed within 24 hours of preparation.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	[Phenyl-(U)-14C]-dicamba	F	144 g as/ha	1	18, 85		Völlmin, S., 1999)
	Sugarcane	[Phenyl-(U)-14C]-dicamba	G	1.12 kg/ha	1	0, 1,2,5,12,21, 28		Butz, R.G. and Atallah, Y.H., 1981

Summary of plant metabolism studies reported in the EU

Plant-uptake, distribution and metabolism of [Phenyl- (U)-14C]-dicamba has been investigated in spring wheat (after foliar application in the field), In spring wheat dicamba was readily absorbed by the leaves after application and only a small amount of radioactivity was translocated to grain. In sugarcane young leaves rapidly absorbed dicamba and only a little part of the absorbed dicamba or its metabolites were translocated to upper or lower untreated leaves. In spring wheat and sugarcane dicamba was quickly metabolised. Hydroxylation of dicamba to 5-OH-dicamba appears to be the major metabolic pathway in the two crops. Conjugation of hydroxylated metabolites was also observed

In summary, the results of these studies indicate that dicamba is metabolised at different rates by different commodities in the same metabolic pathway after foliar application. Besides parent compound, 5-OH dicamba is the only metabolite that is formed in significant quantities, but is further degraded with time. Minor metabolites identified include DCSA and DCGA, which were identified in both, free and conjugated forms. Incorporation of radiolabel led breakdown products of dicamba and its metabolites into natural plant constituents was also observed.

The metabolism of [Phenyl-(U)-14C]-dicamba in wheat, sugarcane, soybeans and cotton appears to follow the same pathways involving the following steps:

- Hydroxylation of dicamba at the 5 position to form 5-OH dicamba (NOA 405873),
- O-demethylation of 5-OH dicamba (NOA 405873) to form DCGA,
- O-demethylation of dicamba to DCSA (NOA 414746),
- Hydroxylation of DCSA to form DCGA,
- Conjugation of 5-OH dicamba (NOA 405873) with glucose to form the β -D-glucoside of 5-OH

dicamba,

- Conjugation of DCSA with glucose to form the β -D-glucoside of DCSA.

Conclusion on metabolism in primary crops

Based on these results rapporteur has evaluated that the metabolic pattern found in cereals covered GAP pattern.

zRMS comments:

The metabolism in primary crops was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies.

According to the EFSA Journal 2011;9(1):1965: *In wheat, dicamba seems to be more extensively metabolised, accounting for 10 % of the TRR in immature plant (forage), and 2 % and 16 % of the TRR respectively in straw and grain at harvest. 5-OH-dicamba is detected as the major metabolite in wheat forage (65 % TRR), but it represents less than 4 % TRR in grain and straw at harvest. Both the parent compound and 5-OH-dicamba were observed in free and conjugated form.*

The metabolism of dicamba proceeds first by hydroxylation to form 5-OH-dicamba, or by demethylation to the DCSA metabolite, both compounds being further degraded to DCGA. Based on these studies, it was proposed to define the residue for monitoring as dicamba and its salts (free and conjugates). For risk assessment, the PRAPeR TC 50 discussed whether 5-OH-dicamba should be included additionally in the residue definition, since it was not observed at significant levels in the edible parts used for human consumption. Finally, and considering the conclusion of the PRAPeR meeting on mammalian toxicology (PRAPeR 83) stating that 5-OH-dicamba is not of higher toxicity than the parent compound, and having regard to the important levels at which this metabolite was observed in the residue trials conducted on pasture, it was agreed to include this metabolite in the residue definition for risk assessment.

Plant residue definition for monitoring (Reg. (EU) 2015/845) – dicamba.

Plant residue definition for risk assessment (EFSA Journal 2011;9(1):1965) – dicamba + 5-OH-dicamba, free and conjugated.

No additional metabolism studies are necessary to support the intended uses on maize.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Mustard	[Phenyl- ¹⁴ C]-dicamba	F	0.56	32, 131,369	At maturity		Moore, P.A., 1989)
	Collards	[Phenyl- ¹⁴ C]-dicamba	F	0.84	30,120	At maturity		Pierotti, M.V., 1995
Root and tuber vegetables	Turnips	[Phenyl- ¹⁴ C]-dicamba	F	0.56	32, 131,369	At maturity		Moore, P.A., 1989)

	Carrots	[Phenyl- ¹⁴ C]-dicamba	F	0.84	30,120	At maturity		Pierotti, M.V., 1995
Cereals	wheat	[Phenyl- ¹⁴ C]-dicamba	F	0.56	32, 131,369	Immature forage stage and at maturity		Moore, P.A., 1989)
	Barley	[Phenyl- ¹⁴ C]-dicamba	F	0.84	30,120, 365	at an intermediate stage (6-8 weeks) and at maturity		Pierotti, M.V., 1995
Pulses and oilseeds	Soybean	[Phenyl- ¹⁴ C]-dicamba	F	0.84	365	forage, hay and at maturity.		Pierotti, M.V., 1995

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

turnips and mustard were grown in soil treated with ¹⁴C-dicamba, equivalent to 0.56 kg as/ha, which corresponds to about 1.5 and 0.75 times the intended use for maize and pasture, respectively. No dicamba, DCSA or 5-OH-dicamba was found in amounts of >0.01 mg/kg 32, 131 and 365 DAT, respectively. Barley, carrots and collard greens were planted as rotational crops to maize treated with ¹⁴C-dicamba, equivalent to 0.840 kg as/ha and corresponding to about twice the rate according to the intended use for maize and pasture. TRR was < 0.04 mg/kg 120 DAT. TRR 30 DAT was high (1.022 mg/kg in carrot roots and 0.272 mg/kg in barley grain). Since no residues of dicamba, DCSA and 5-OH-dicamba was found in the study, where wheat, turnips and mustard were used as rotational crops it is not expected either that the residues found in barley, carrots and collard greens 30 DAT will be due to dicamba, DCSA or 5-OH-dicamba. They could be due to incorporation of ¹⁴CO₂ or other breakdown products into plant constituents such as lignin or cellulose.

Conclusion on metabolism in rotational crops

There will therefore be no restriction of planting or sowing succeeding and rotational crops

zRMS comments:

The metabolism in rotational crops was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies.

According to the EFSA Journal 2011;9(1):1965 no parent but only 5-OH and DCSA were identified in the rotational crops. Only DCSA was identified in soil.

The metabolic pathway in rotational crops is sufficiently addressed and no additional metabolism studies are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
Pasteurisation (20 minutes, 90°C, pH 4)	14C- dicamba: 100.5 14C- dicamba: 100.9	Grout, S.J., 2003
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	14C- dicamba: 106.0 14C- dicamba: 104.2	Grout, S.J., 2003
Sterilisation (20 minutes, 120°C, pH 6)	14C- dicamba: 110.4 14C- dicamba: 104.8	Grout, S.J., 2003

Conclusion on nature of residues in processed commodities

Dicamba is hydrolytically stable under conditions representative of pasteurisation, baking, brewing and boiling and sterilisation.

zRMS comments:

The nature of residues in processed commodities was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies and they are not required. Dicamba is hydrolytically stable under conditions representative of pasteurisation, baking, brewing and boiling and sterilisation.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals(wheat and sugar cane Pulses/oilseeds(soybean and cotton)
Rotational crops covered	Leafy crops (mustard and collard greens), root vegetables (carrot and turnips) and cereals (wheat and barley)
Metabolism in rotational crops similar to metabolism in primary crops?	No parent, 5-OH-dicamba and DCSA identified in the rotational crops. DCSA identified in soil.
Processed commodities	Not provided and not required.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Dicamba and its salts and conjugated dicamba expressed as dicamba. Reg. (EU) 2015/845 - dicamba
Plant residue definition for risk assessment	Dicamba + 5-OH-dicamba, free and conjugated
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA Journal 2011;9(1):1965).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[Phenyl-(U)- ¹⁴ C]-dicamba	3	10 mg and 1000 mg	5	Milk	twice daily	Guirguis, A.S., Yu, C. C., 1994)
						Urine and faeces	Twice daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[Phenyl-(U)- ¹⁴ C]-dicamba	8	0.6 mg and 30 mg/kg	5	Eggs	daily	Nietschmann D. A. and Yu, C. C. , 1994)
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

In summary dicamba was, after oral administration to lactating cow, lactating goat, laying hens and rats, quickly adsorbed and eliminated in excreta (mainly via urine). A very low transfer of residues into tissues, milk and eggs was observed. Therefore residue levels in tissues were low. Unchanged dicamba was the major compound observed in animal excreta, tissues and hen eggs representing between 63 – 102 % of the TRR. DCSA represented 8-21 % of the TRR in the cow (highest in liver) and 1-12 % (0.0001 – 0.0057 mg/kg) of the TRR in the goat (highest in liver). The metabolites 2,5-dichlorophenol (DCP) and glucuronide-conjugate of DCSA were detected in cow urine in amounts of 2-4 % and 2-3 % of the TRR, respectively. The metabolite 2-amino-3,6-dichloro-phenol (2A36DCP) was found in hen liver (36 % of TRR, 0.001 mg/kg).

Based on the work performed with cow, goat, hen and rat the metabolism of ¹⁴C-dicamba appears to follow the same pathways comprising the steps detailed below (see figure B.7.2.1)

- O-demethylation of dicamba to DCSA (NOA 414746)
- Conjugation of DCSA (NOA 414746) with glucuronic acid
- Decarboxylation of DCSA (NOA 414746) to 2,5-dichlorophenol (DCP)
- Decarboxylation of DCSA (NOA 414746) followed by substitution by an amino group to form 2-amino-3,6-dichlorophenol (2A36DCP)
- Hydroxylation of dicamba to 5-OH dicamba (NOA 405873).

Conclusion on metabolism in livestock

Based on these results rapporteur has evaluated that the metabolic pattern found in cereals covered GAP pattern.

zRMS comments:

The metabolism in livestock was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies and they are not required.

According to the EFSA Journal 2011;9(1):1965: *Metabolism in animals was considered in cow, goat and poultry, using ¹⁴C-dicamba. The transfer in fat, milk and eggs was limited, the highest TRRs being observed in kidney and liver. Dicamba (free and conjugated) was by far the major compound*

identified in all animal matrices, accounting for more than 50 % of the TRR. In addition, DCSA was also observed in ruminants, but only in kidney and liver, up to 21 % of the TRR. 5-OH-dicamba was not detected in animal matrices, except in urine and excreta, but at insignificant levels and proportions (< 0.01 % TRR). Having regard to the high levels of 5-OH-dicamba in grass, and consequently its significant intake by ruminants (c.a. 1.5 mg/kg bw/day), the PRAPeR TC 50 meeting of experts discussed whether a specific metabolism study using this metabolite needs to be required. The experts were of the opinion that a similar pathway to the parent is expected for 5-OH-dicamba, this metabolite being probably more extensively excreted than the parent compound since it is more polar. This assertion is supported by the results of the cow feeding study conducted with 5-OH-dicamba, where this metabolite was almost not detected in any matrices, except in kidney, at the 5N dose rate. It was therefore concluded that a specific ruminant metabolism study should not be required for 5-OH-dicamba. Finally, dicamba and its salts (free and conjugates) was proposed to define the residue for monitoring, and MRLs were derived for ruminant products from the feeding study conducted with the parent dicamba. For risk assessment, considering the lower ADI of 0.01 mg/kg bw/day proposed for the metabolite DCSA when compared to the parent compound, the PRAPeR TC 50 meeting of experts proposed to define the residue as parent dicamba and DCSA (free and conjugates). However, after the meeting, the consumer risk assessment conducted for DCSA, taking into account the expected residue levels in kidney and liver, showed highest intakes below 0.2 % of the ADI. Having regard to the very low contribution of the DCSA metabolite to the consumer exposure and considering that the animal intake will not be increased if additional uses are envisaged, EFSA is of the opinion that the residue definition for risk assessment should be limited to the parent dicamba only.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	Milk: 20 days
	-
Animal residue definition for monitoring	Dicamba and its salts and conjugated dicamba expressed as dicamba Reg. (EU) 2015/845 - dicamba
Animal residue definition for risk assessment	Dicamba (free and conjugated)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA Journal 2011;9(1):1965)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of CHR/H/DIK 480 SL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize Grain	EFSA Journal 2011;9(1):1965 (KCP 6.3/01 – 03)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg as/ha, BBCH 16, PHI 14d, outdoor E: 6 x <0.01, 3x <0.05 for dicamba and 5-OH dicamba RAE: 6 x 0.01, 3x <0.05 for dicamba and 5-OH dicamba RA: 6 x 0.02, 3 x 0.1	N/A				
	Overall supporting data for cGAP	N-EU	E: 6 x <0.01, 3x <0.05 for dicamba and 5-OH dicamba RAE: 6 x 0.01, 3x <0.05 for dicamba and 5-OH dicamba RA: 6 x 0.02, 3 x 0.1	<0.01 E: 0.01 RA: 0.02	<0.015 E:0.05 RA: 0.1	0.05 0.207	0.5	Yes
Maize straw:	EFSA Journal 2011;9(1):1965 (KCP 6.3/01 – 03)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg as/ha, BBCH 16, PHI 14d, outdoor E: 3 x <0.05 for dicamba and 5-OH dicamba RA: 3 x 0.05 for dicamba and 5-OH dicamba	N/A				
	Overall supporting data for cGAP	N-EU	E: 3 x <0.05 for dicamba and 5-OH dicamba RA: 3 x 0.05 for dicamba and 5-OH dicamba	<0.05	<0.05		0.5	Yes
Maize cobs	EFSA Journal 2011;9(1):1965 (KCP 6.3/01 – 03)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg as/ha, BBCH 16, PHI 14d, outdoor E: 4 x <0.01 for dicamba and 5-OH dicamba RA: 4 x <0.01 for dicamba and 5-OH dicamba	N/A				
	Overall supporting data for cGAP	N-EU	E: 4 x <0.01 for dicamba and 5-OH dicamba RA: 4 x <0.01 for dicamba and 5-OH dicamba	<0.01	<0.01		0.5	Yes

Maize Steam with leaves:	EFSA Journal 2011;9(1):1965 (KCP 6.3/01 – 03)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg as/ha, BBCH 16, PHI 14d, outdoor E: 0.01, 0.02, 0.03, 0.28 for dicamba <0.01, 0.03, 0.03, 0.05 for 5-OH dicamba RA: 0.01, 0.02, 0.03, 0.28 for dicamba <0.01, 0.03, 0.03, 0.05 for 5-OH dicamba	N/A				
	Overall supporting data for cGAP	N-EU	E: 0.01, 0.02, 0.03, 0.28 for dicamba <0.01, 0.03, 0.03, 0.05 for 5-OH dicamba RA: 0.01, 0.02, 0.03, 0.28 for dicamba <0.01, 0.03, 0.03, 0.05 for 5-OH dicamba	0.025 fro dicamba 0.03 for 5-OH dicamba	0.28 for dicamba 0.05 for 5- OH dicamba		0.5	Yes

* Source of EU MRL: Reg. (EU) 2015/845

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

zRMS comments:

The magnitude of residues in plants was reviewed during the Annex I inclusion process. The Applicant has not provided any new studies.

9 trials in NEU on maize were evaluated and are acceptable and sufficient to support the use on maize proposed for CHR/H/DIK 480 SL. Residues of dicamba in maize grain were all below the LOQ (0.01 mg/kg or 0.05 mg/kg). No MRL (0.5 mg/kg, Reg. (EU) 2015/8450) exceedances are expected.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Since all residues for formulation CHR/H/DIK 480 SL containing dicamba in maize are below 0.01 mg/kg there is no need to perform risk assessment for dietary burden. There will be no risk for domestic animals feeding grains and green material in accord to the label.

Since all residues for formulation CHR/H/DIK 480 SL containing dicamba in straw of maize are above 0.01 mg/kg there is need to perform risk assessment for dietary burden.

Table 7.2-10: Input parameters for dietary burden calculation (DAR for dicamba)

Commodity	STMR [mg/kg]	HR [mg/kg]
Grass – forage (fresh)	5.12	13.80
Grass – hay	5.12	13.80
Grass – silage	5.12	13.80
Corn, field – forage/silage	0.025	0.28
Corn, field – stover (fodder)	0.025	0.28
Corn, pop – stover (fodder)	0.025	0.28
Corn, field - grain	0.01	-
Corn, field – milled by-pdts	0.01	-
Corn, field – hominy meal	0.01	-
Corn, field – gluten feed	0.01	-
Corn, field – gluten, meal	0.01	-
Distiller's grain – dried	0.01	-

Animal burden calculation												Dicamba							
According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"																			
Maximum Intake	Cattle								Sheep										
	Beef				Dairy				Ram/Ewe				Lamb						
	500 kg 12 kg				650 kg 25 kg				75 kg 2.5 kg				40 kg 1.7 kg						
(mg/kg bw/d)	0.663				1.275				1.748				1.174						
Contributor 1	Grass	forage (fresh)		50	Grass	silage		60	Grass	forage (fresh)		95	Grass	forage (fresh)					
Contributor 2	Corn, field	gluten feed		30	Corn, field	gluten feed		30	Corn, field	gluten feed		5	Corn, field	gluten feed					
Contributor 3	Corn, field	grain		20	Corn, field	grain		10				0	Corn, field	grain					
Contributor 4																			
Median intake	0.2463				0.4734				0.6486				0.4361						
Maximum Intake	Swine								Intakes >0.004 mg/kg bw/d are highlighted										
	Breeding				Finishing														
	260 kg 6 kg				100 kg 3 kg														
(mg/kg bw/d)	0.255				0.001														
Contributor 1	Grass	forage (fresh)		20	Corn, field	gluten feed		20											
Contributor 2	Corn, field	gluten feed		20	Corn, field	grain		70											
Contributor 3	Corn, field	grain		60															
Contributor 4																			
Median intake	0.095				0.001														
Maximum Intake	Poultry																		
	Broiler				Layer											Turkey			
	1.7 kg 0.12 kg				1.9 kg 0.13 kg											7 kg 0.5 kg			
(mg/kg bw/d)	0.001				0.006				0.001										
Contributor 1	Corn, field	milled bypdt		60	Corn, field	forage/silage		10	Corn, field	hominy meal		20							
Contributor 2	Corn, field	grain		40	Corn, field	hominy meal		20	Corn, field	grain		50							
Contributor 3					Corn, field	grain		70											
Contributor 4																			
Median intake	0.001				0.002				0.001										
Intakes expressed on the dry mater basis (mg/kg DM)																			
mg/kg DM	Cattle				Sheep				Swine										
	Beef	Dairy			Ram/Ewe	Lamb			Breeding	Finishing									
Maximum	27.62	33.14			52.4	27.62			11.06	0.02									
Median	10.26	12.31			19.46	10.26			4.12	0.02									
Poultry																			
	Broiler	Layer			Turkey		Intake >0.1 mg/kg DM in red characters												
Maximum	0.01	0.09			0.02														
Median	0.01	0.03			0.02														

zRMS comments:

The calculations presented above were made taking into account the STMR and HR values from field trials for maize and pastures assessed in the DAR for dicamba. Animal Model 2017 was used.

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.473	1.275	12.31	33.14	Dairy cattle	Grass	silage	Yes
Cattle (dairy only)	0.473	1.275	12.31	33.14	Dairy cattle	Grass	silage	Yes
Sheep (all diets)	0.649	1.748	19.46	52.44	Ram/Ewe	Grass	forage (fresh)	Yes
Sheep (ewe only)	0.649	1.748	19.46	52.44	Ram/Ewe	Grass	forage (fresh)	Yes
Swine (all diets)	0.095	0.255	4.12	11.06	Swine (breeding)	Grass	forage (fresh)	Yes

Poultry (all diets)	0.002	0.006	0.03	0.09	Poultry layer	Corn. field	forage/silage	Yes
Poultry (layer only)	0.002	0.006	0.03	0.09	Poultry layer	Corn. field	forage/silage	Yes

The trigger value is exceeded therefore livestock feeding studies are required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Since dicamba residues in cereals grains and green matter are below 0.01 mg/kg, therefore no livestock feeding studies are necessary.

According to DAR Dicamba, Volume 3, Section b7 and EFSA Journal 2011;9(1):1965:
 Since residues of dicamba in straw of maize are ≥ 0.1 mg/kg livestock feeding studies are required. Since the metabolism study in goat has shown that the metabolic patterns in the rats and goats are similar a pig feeding study is not required. Livestock feeding studies in dairy cows and laying hens has been submitted. The metabolite 5-OH-dicamba is not proposed to be in the residue definition for risk assessment and monitoring for animal products.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant	Poultry	Pig
Expected intakes* by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes ^a 69 mg/kg DM dairy/beef cattle	No 0.02 mg/kg DM	No 0.02 mg/kg DM
Potential for accumulation (yes/no):	No	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	n/a	n/a
	- Cow feeding study: Residues of dicamba for the feeding rate of 120 mg/kg DM (2.8 mg/kg bw) corresponding to a c.a. 1N dose rate for dairy and beef cattle. - Laying hen study: Residues of dicamba for the feeding rate of 2 mg/kg diet (c.a. 100N). Residue levels in matrices : mean (max) mg/kg		
Muscle	0.012 (0.014)	<0.01	
Liver	0.066 (0.070)	<0.01	
Kidney	0.282 (0.288)	<0.01	
Fat	0.025 (0.034)	<0.01	
Milk	0.05 (0.06)		
Eggs		<0.01	

^a: Intake calculated for the parent dicamba only. Additional intake of 5-OH-dicamba estimated to be 39.5 mg/kg DM (equivalent to 1.4 and 1.7 mg/kg bw for dairy and beef cattle, respectively). Residues of 5-OH-dicamba not expected to be present in animal matrices since residues ≤ 0.01 mg/kg in all animal products (<0.005 mg/kg in milk) in a feeding study conducted with 5-OH-dicamba and for the dose rate of 60 mg/kg DM (c.a. 1.5N).

a) Conclusion for lactating cow:

Lactating cows were dosed with 5-OH-dicamba at three feed levels: 400 mg/cow/day, 1200 mg/cow/day and 4000 mg/cow/day. No residues were found in milk above the LOQ except for one sample in the 10X dose-group. No residues were found in tissues in the 1x and 3x dose levels except the kidney where residues of 0.02 and 0.01 mg/kg were found, respectively. In the 10x dose level low residue levels (0.02-0.06 mg/kg) besides the kidney and the

blood were seen in all tissues. In blood and kidney average residues of 0.15 mg/kg and 0.27 mg/kg, respectively were seen.

b) Conclusion for laying hen:

At the highly exaggerated dose rates of 6 mg/kg feed no residues were detected in eggs, adipose tissues, skin breast or leg muscles. For the 2 mg/kg level, no skin, breast or leg muscles were analyzed. Low residues were seen in the liver (0.012-0.023 mg/kg) at the dose rate 6 mg/kg.

After a 3-day withdrawal period, dicamba residues were below the LOQ in liver, breast and leg tissues but present in the adipose of one hen (0.020-0.081 mg/kg) and the skin of two hens (<0.010 to 0.034 mg/kg) at the 20 mg/kg dose level. An isolated residue value in the skin of one single hen indicated a residue of 0.081 mg/kg. This sample did not physically appear representative; therefore, another sample was prepared and on analysis yielded a residue value of 0.020 mg/kg. No dicamba residues were detected in eggs.

Additionally performed MRL calculation below:

Table 7.2-11: Input parameters for MRL calculation for animal matrices

Bovine	Matrix	Feeding levels		Residue [mg/kg]
		Mg/kg bw	Mg/kg DM	
	Muscle	0.933	40	0.010
		2.800	120	0.012
		9.33	400	0.030
	Fat	0.933	40	
		2.800	120	0.025
		9.33	400	0.047
	Liver	0.933	40	0.026
		2.800	120	0.066
		9.33	400	0.207
	Kidney	0.933	40	0.154
		2.800	120	0.282
		9.33	400	0.646
	Milk	0.933	40	0.020
		2.800	120	0.050
		9.33	400	0.360
Poultry	Matrix	Feeding levels		Residue [mg/kg]
		Mg/kg bw	Mg/kg DM	
	Muscle	1.030	2	0.01
		3.109	6	0.01
		10.36	20	0.01
	Fat	1.030	2	0.01
		3.109	6	0.01
		10.36	20	0.068
	Liver	1.030	2	0.01
		3.109	6	0.023
		10.36	20	0.053
	Kidney	1.030	2	0.010
		3.109	6	0.010
		10.36	20	0.025
	Eggs	1.030	2	0.01
		3.109	6	0.01
		10.36	20	0.01

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
			STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)				
	Mean	Highest						
Cattle (all diets)								
Closest feeding level ^(a) :	0.933	mg/kg bw	0.7 N Dairy cattle (highest diet)					
Muscle	0.01	0.01	0.01	0.01	0.02	n.c.	0.01	0.01
Fat	0.02	0.02	0.01	0.03	0.04	n.c.	0.01	0.03
Liver	0.03	0.03	0.01	0.04	0.04	n.c.	0.01	0.04
Kidney	0.15	0.15	0.08	0.21	0.3	n.c.	0.08	0.21
Cattle (dairy only)								
Closest feeding level ^(a) :	0.933	mg/kg bw	0.7 N Dairy cattle					
Milk ^(b)	0.02	0.02	0.01	0.03	0.03	n.c.	0.01	0.03
Sheep (all diets)								
Closest feeding level ^(a) :	0.933	mg/kg bw	0.5 N Ram/Ewe (highest diet)					
Muscle	0.01	0.01	0.01	0.02	0.02	n.c.	0.01	0.02
Fat	0.02	0.02	0.02	0.04	0.05	n.c.	0.02	0.04
Liver	0.03	0.03	0.02	0.05	0.05	n.c.	0.02	0.05
Kidney	0.15	0.15	0.11	0.29	0.3	n.c.	0.11	0.29
Sheep (dairy only)								
Closest feeding level ^(a) :	0.933	mg/kg bw	0.5 N Ewe					
Milk ^(b)	0.02	0.02	0.01	0.04	0.04	n.c.	0.01	0.04
Swine								
Closest feeding level ^(a) :	0.933	mg/kg bw	3.7 N Breeding (highest diet)					
Muscle	0.01	0.01	0.00	0.00	0.003	n.c.	0.00	0.00
Fat	0.02	0.02	0.00	0.01	0.007	n.c.	0.00	0.01
Liver	0.03	0.03	0.00	0.01	0.008	n.c.	0.00	0.01
Kidney	0.15	0.15	0.02	0.04	0.05	n.c.	0.02	0.04
Poultry (all diets)								
Closest feeding level ^(a) :	1.03	mg/kg bw	164.4 N Layer (highest diet)					
Muscle	0.01	0.01	0.00	0.00	0.001			
Fat	0.01	0.01	0.00	0.00	0.001			
Liver	0.01	0.01	0.00	0.00	0.001			
Poultry (layer only)								
Closest feeding level ^(a) :	1.03	mg/kg bw	164.4 N Layer					
Eggs ^(c)	0.01	0.01	0.00	0.00	0.001			
(a): Closest feeding level and N dose rate related to the maximum dietary burden.								
(b): Highest residue level from day D1 to day D2 (daily mean of X cows).								
(c): Highest residue level from day D1 to day D2 (daily mean of Y laying hens).								

There will no risk for domestic animals feeding grains and green material after application of CHR/H/DIK 480 SL in accord to the label.

zRMS comments:

There is no risk for animal MRL to be exceeded.

Animal commodity	MRL proposal (mg/kg)	MRL (Reg. (EU) 2015/845)
Cattle (all diets)		
Muscle	0.02	0.05
Fat	0.04	0.07
Liver	0.04	0.7

Kidney	0.3	0.7
Cattle (dairy only)		
Milk	0.03	0.5
Sheep (all diets)		
Muscle	0.02	0.05
Fat	0.05	0.07
Liver	0.05	0.7
Kidney	0.3	0.7
Sheep (dairy only)		
Milk	0.04	0.2
Swine		
Muscle	0.003	0.05
Fat	0.007	0.07
Liver	0.008	0.7
Kidney	0.05	0.7
Poultry (all diets)		
Muscle	0.001	0.02
Fat	0.001	0.04
Liver	0.001	0.07
Poultry (layer only)		
Eggs	0.001	0.05

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Not required, since no significant residues (all residues <0.01 mg/kg) occur in the plant or plant product for further processing, and TMDI <10 % of ADI

zRMS comments

zRMS agrees with the Applicant.

7.2.6 Magnitude of residues in representative succeeding crops

DT90 is <100 days, therefore no studies are needed according to guidelines. No residues > 0.01 mg/kg of dicamba, DCSA or 5-OH-dicamba were seen 32, 131 and 365 DAT, respectively in mustards tops, turnips tops and roots, wheat forage, wheat straw, wheat grain and wheat chaff in a confined rotational crop study

zRMS comments:

zRMS agrees, no study dealing with magnitude of residues in succeeding crops is needed.

7.2.7 Other / special studies (KCA6.10. 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/DIK 480 SL Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 (if applicable)				
Maize	0.5	MRL	0.5	MRL

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	1 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	1 % (based on NL toddler)
UESTI (% ARfD) according to EFSA PRIMo*	Maize: 1 % (based on unprocessed for children) Maize: 0.4 % (based on unprocessed for adult) Maize: 4 % (based on processed for children) Maize: 2 % (based on processed for adult)

* include raw and processed commodities if both values are required for PRIMo

** if national model is available


The proposed uses of dicamba in the formulation CHR/H/DIK 480 SL do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:

Consumer risk assessment was conducted using EFSA PRIMo rev. 3.1.

In addition the calculation of the TMDI was performed taking into account all current MRLs (Reg. (EU) 845/2015).

The current MRLs for plant commodities (except soybeans) do not consider the residue level of the metabolite 5-OH-dicamba. However residue data for intended uses on maize for the sum of dicamba and 5-OH dicamba expressed as dicamba are below the current MRL therefore the consideration of CF is not necessary in this case.

 European Food Safety Authority EFSA PRIMo revision 3.1: 2021/01/06		<div>Dicamba</div> <div>LOQs (mg/kg) range from: 0.05 to: 0.50</div> <div>Toxicological reference values</div> <div>ADI (mg/kg bw/day): 0.3 ARD (mg/kg bw): 0.3</div> <div>Source of ADI: EFSA 2011 Source of ARD: EFSA 2011</div> <div>Year of evaluation: 2011 Year of evaluation: 2011</div>		<div>Input values</div> <div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											
TMDI(NED) calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (% of ADI)	Commodity / group of commodities	2nd contributor to MS diet (% of ADI)	Commodity / group of commodities	3rd contributor to MS diet (% of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ under assessment (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	19%	GEMS/Food G11	57.73	12%	Soybeans	2%	Wheat	2%	Barley	0.4%	
	17%	GEMS/Food G10	51.36	11%	Soybeans	3%	Wheat	1%	Barley	0.3%	
	16%	NL toddler	48.50	10%	Milk: Cattle	3%	Wheat	1%	Maize/corn	0.6%	
	14%	GEMS/Food G08	40.90	7%	Soybeans	3%	Wheat	2%	Barley	0.3%	
	13%	GEMS/Food G15	39.04	6%	Soybeans	3%	Wheat	2%	Barley	0.3%	
	13%	GEMS/Food G07	37.78	6%	Soybeans	3%	Wheat	1%	Barley	0.3%	
	11%	GEMS/Food G06	32.99	5%	Wheat	4%	Soybeans	0.6%	Sugar cane	0.3%	
	9%	UK infant	27.12	6%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Muscle/meat	0.2%	
	9%	NL child	25.56	4%	Milk: Cattle	3%	Wheat	0.7%	Soybeans	0.5%	
	8%	FR child 3-15 yr	23.62	4%	Milk: Cattle	3%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	
	8%	FR toddler 2-3 yr	23.48	5%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	
	8%	DE child	23.32	3%	Milk: Cattle	3%	Wheat	0.4%	Apples	0.4%	
	7%	UK toddler	20.14	3%	Milk: Cattle	3%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	
	7%	DK child	19.84	3%	Wheat	2%	Milk: Cattle	0.9%	Rye	0.2%	
	6%	RO general	17.67	3%	Wheat	2%	Milk: Cattle	0.2%	Maize/corn	0.3%	
	6%	ES child	17.20	3%	Wheat	2%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.2%	
	6%	DE general	16.50	2%	Milk: Cattle	1%	Wheat	1%	Barley	0.3%	
	5%	SE general	16.26	2%	Wheat	2%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.3%	
	5%	DE women 14-50 yr	14.95	2%	Milk: Cattle	1%	Wheat	0.4%	Barley	0.3%	
	5%	IT toddler	14.52	4%	Wheat	0.2%	Other cereals	0.0%	Apples	0.1%	
	4%	NL general	13.06	1%	Milk: Cattle	1%	Wheat	0.7%	Barley	0.3%	
	4%	PT general	12.48	3%	Wheat	1%	Soybeans	0.1%	Potatoes	0.2%	
	4%	ES adult	11.52	2%	Wheat	1%	Barley	0.8%	Milk: Cattle	0.2%	
	4%	FR infant	10.98	3%	Milk: Cattle	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.2%	
3%	E adult	9.80	2%	Wheat	0.7%	Milk: Cattle	0.2%	Asparagus	0.4%		
3%	IT adult	9.18	3%	Wheat	0.1%	Other cereals	0.0%	Apples	0.1%		
3%	FR adult	8.33	1%	Wheat	0.7%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.3%		
2%	UK vegetarian	6.57	1%	Wheat	0.5%	Milk: Cattle	0.0%	Barley	0.1%		
2%	DK adult	6.06	0.9%	Milk: Cattle	0.7%	Wheat	0.1%	Bovine: Muscle/meat	0.1%		
2%	UK adult	5.96	1%	Wheat	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%		
2%	LT adult	5.82	0.7%	Wheat	0.7%	Milk: Cattle	0.2%	Rye	0.1%		
2%	FI adult	4.57	0.9%	Coffee beans	0.2%	Wheat	0.1%	Rye	1%		
1%	FI 3 yr	4.47	0.8%	Wheat	0.2%	Barley	0.1%	Rye	0.2%		
1%	E child	4.43	0.8%	Wheat	0.8%	Milk: Cattle	0.0%	Rice	0.0%		
1%	FI 6 yr	3.60	0.6%	Wheat	0.1%	Barley	0.1%	Rye	0.2%		
0.2%	PL general	0.64	0.1%	Apples	0.1%	Potatoes	0.0%	Tomatoes	0.1%		
Conclusion: The estimated long-term dietary intake (TMDI(NED)) was below the ADI. The long-term intake of residues of Dicamba is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

The TMDI does not exceed ADI. Additional calculations are not required.

An acute dietary risk assessment was conducted for maize and animal commodities considering MRLs which is a significant overestimation considering the STMR and HR values shown in this dossier.

Acute risk assessment / children				Acute risk assessment / adults / general population				Acute risk assessment / children				Acute risk assessment / adults / general population												
Details - acute risk assessment / children				Details - acute risk assessment / adults				Hide IESTI new calculations				Show IESTI new calculations												
The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.								The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.																
The calculation is based on the large portion of the most critical consumer group.								The calculation is based on the large portion of the most critical consumer group.																
Show results for all crops								Show results for all crops																
Unprocessed commodities	Results for children				Results for adults				IESTI new				IESTI new											
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI new):				No. of commodities for which ARfD/ADI is exceeded (IESTI new):											
	---				---				---				---											
	IESTI				IESTI				IESTI new				IESTI new											
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)							
	21%		Milk: Cattle		0.5 / 0.5		62		6%		Milk: Cattle		0.5 / 0.5		19		21%		Milk: Cattle		0.5 / 0.5		62	
	2%		Bovine: Liver		0.7 / 0.7		5.6		1%		Milk: Goat		0.2 / 0.2		3.7		2%		Bovine: Liver		0.7 / 0.7		5.6	
	2%		Bovine: Edible offals (other than liver)		0.7 / 0.7		5.1		1%		Milk: Sheep		0.2 / 0.2		3.0		2%		Bovine: Edible offals (other than liver)		0.7 / 0.7		5.1	
	2%		Milk: Goat		0.2 / 0.2		4.8		0.9%		Bovine: Muscle		0.5 / 0.5		2.8		2%		Milk: Goat		0.2 / 0.2		4.8	
	1%		Bovine: Muscle		0.5 / 0.5		3.6		0.9%		Bovine: Liver		0.7 / 0.7		2.8		1%		Bovine: Muscle		0.5 / 0.5		3.6	
1%		Maze/corn		0.5 / 0.5		3.4		0.8%		Bovine: Edible offals (other than liver)		0.7 / 0.7		2.3		1%		Maze/corn		0.5 / 0.5		3.4		
0.9%		Bovine: Kidney		0.7 / 0.7		2.6		0.7%		Sheep: Liver		0.7 / 0.7		2.0		0.9%		Bovine: Kidney		0.7 / 0.7		2.6		
0.7%		Swine: Edible offals (other than liver)		0.7 / 0.7		2.1		0.6%		Swine: Edible offals (other than liver)		0.7 / 0.7		1.8		0.7%		Swine: Edible offals (other than liver)		0.7 / 0.7		2.1		
0.3%		Swine: Kidney		0.7 / 0.7		0.89		0.5%		Bovine: Kidney		0.7 / 0.7		1.5		0.3%		Swine: Kidney		0.7 / 0.7		0.89		
0.3%		Bovine: Liver		0.7 / 0.7		0.86		0.5%		Bovine: Kidney		0.7 / 0.7		1.5		0.3%		Bovine: Liver		0.7 / 0.7		0.86		
0.2%		Milk: Sheep		0.2 / 0.2		0.71		0.4%		Maze/corn		0.5 / 0.5		1.1		0.2%		Milk: Sheep		0.2 / 0.2		0.71		
0.2%		Eggs: Chicken		0.02 / 0.02		0.62		0.3%		Bovine: Other products		0.05 / 0.05		1.00		0.2%		Eggs: Chicken		0.02 / 0.02		0.62		
0.2%		Swine: Muscle/meat		0.05 / 0.05		0.61		0.3%		Swine: Liver		0.05 / 0.05		0.81		0.2%		Swine: Muscle/meat		0.05 / 0.05		0.61		
0.1%		Other farmed animals: Muscle/meat		0.05 / 0.05		0.35		0.2%		Sheep: Edible offals (other than liver)		0.7 / 0.7		0.48		0.1%		Other farmed animals: Muscle/meat		0.05 / 0.05		0.35		
0.1%		Poultry: Muscle/meat		0.02 / 0.02		0.34		0.1%		Poultry: Liver		0.07 / 0.07		0.33		0.1%		Poultry: Muscle/meat		0.02 / 0.02		0.34		
Expand/collapse list								Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)																
---								---																
Processed commodities	Results for children				Results for adults				Results for children				Results for adults											
	No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):											
	---				---				---				---											
	IESTI				IESTI				IESTI new				IESTI new											
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)							
	4%		Maize / oil		0.5 / 12.5		12		2%		Maize / oil		0.5 / 12.5		6.3		4%		Maize / oil		0.5 / 12.5		6.3	
	0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.5%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1	
	0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.5%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1	
	0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.5%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1	
	0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.5%		Maize / processed (not spec)		1.1 / 1.1		1.1		0.4%		Maize / processed (not spec)		1.1 / 1.1		1.1	
Expand/collapse list								Expand/collapse list																
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Dicamba is unlikely to present a public health risk.								Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Dicamba is unlikely to present a public health risk.																

The calculated IESTI does not exceed ARfD.

TMDI (% ADI) according to EFSA PRIMo	19 % (based on GEMS/FOOD G11)
IESTI (% ARfD) according to EFSA PRIMo	21% milk: cattle 2% bovine: liver

	2% bovine: edible offals 2% milk: goat 1% maize/corn Processed commodities 4% maize/oil
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The proposed use of CHR/H/DIK 480 SL on maize do not represent unacceptable acute and chronic risk for consumers.

7.3 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The following paragraphs are to be considered as proposals, based on “standard” criteria.
Not relevant. The product contains only one active substance.

7.4 References

EFSA Journal 2011;9(1):1965

DAR DICAMBA . Volume 3. Annex B. part 3. B.7. November 2007

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	Jimenez.N.C.	1995	Stability of Dicamba and 5-Hydroxy Dicamba in Stored Frozen Field Corn Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 127 GLP Not Published Syngenta File N° SAN837/5433	N	SYN
KCP 6.1/02	Formanski. L.J.	1996	Stability of dicamba and 3,6-dichlorosalicylic acid in stored frozen beef tissues and milk Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 151 GLP Not Published Syngenta File N° SAN837/5242	N	SYN
KCP 6.2.1/01	Völlmin. S.	1999	Metabolism and Behaviour of Dicamba in Field grown Spring Wheat after Application of [Phenyl-(U)-14C] Material Novartis Crop Protection AG. Basel. Switzerland. Report No 97SV01 GLP Not Published Syngenta File N° SAN837/5879	N	SYN
KCP 6.2.1/02	Butz. R.. Atallah. Y.	1981	Metabolic Fate of Dicamba in Sugarcane Plants Novartis Crop Protection AG. Basel. Switzerland Velsicol Environmental Science. Chicago. United States. Report No 24 Not GLP Not Published Syngenta File N° SAN837/5160	N	SYN
KCP 6.2.1/03	Butz. R.. Atallah. Y.	1981	Extractability of Dicamba Residues from Sugarcane Leaves Novartis Crop Protection AG. Basel. Switzerland	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Velsicol Environmental Science. Chicago. United States. Report No 13 Not GLP Not Published Syngenta File N° SAN837/5534		
KCP 6.2.2/01	xxxxxxx	1980	Metabolic Fate of the Herbicide Dicamba in a Lactating Cow xxxxxxxxxxxxxxxx Published Syngenta File N° SAN837/5145	Y	SYN
KCP 6.2.2/02	Guirguis. A.S.. Yu. C.C.	1994	Metabolism of Dicamba in Lactating Goats Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 28 GLP Not Published Syngenta File N° SAN837/5286	N	SYN
KCP 6.2.2/03	Yu. C.C.. Atallah. Y.H.	1983	Pharmacokinetics and Metabolism of 14C-dicamba in Hens Novartis Crop Protection AG. Basel. Switzerland Velsicol Chemical Corporation. Chicago. United States. Report No 65 Not GLP Not Published Syngenta File N° SAN837/5254	N	SYN
KCP 6.2.2/04	Nietschmann. D.A. Yu C.C.	1994	Dicamba: Metabolism in Laying Hens Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 25 GLP Not Published Syngenta File N° SAN837/5285	N	SYN
KCP 6.3/01	Taylor. D.T. et al.	1984	Determination of Dicamba and 5-Hydroxy Dicamba. A-7254 B. in Austrian Maize Grain and Straw Novartis Crop Protection AG. Basel. Switzerland Hazleton Europe Ltd.. Harrogate. North Yorkshire. United Kingdom. Report No 206/4 GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not Published Syngenta File N° SAN837/0025		
KCP 6.3/02	Hertl. P.	1995	Determination of residues of DICAMBA in Corn (Zea mais) after application of BANVEL 4S or SAN 845 H 70 WG under field conditions in the Federal Republic of Germany. 1993. Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Ltd.. Huningue. France. Report No R10280 GLP Not Published Syngenta File N° SAN837/5434	N	SYN
KCP 6.3/03	Kaethner. M.	1993	Determination of residues of Dicamba and 5-OH Dicamba on corn after application of two different formulations. SAN 845 H 70 WG 001 SP and BANVEL 4S. and one mixture of SAN 845 H + SAN 1287 H at 6 leaf stage under field conditions in France Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Ltd.. Huningue. France. Report No BS3941 GLP Not Published Syngenta File N° SAN837/5444	N	SYN
KCP 6.4.1/01	Tims. M.O.. Weissenburger. B.R.	1979	EFFECT OF FEEDING DICMABA TO DAIRY CATTLE (Residues in Milk) Novartis Crop Protection AG. Basel. Switzerland Brian Christensen Companies. Inc.. Minnetonka. United States. Report No 379 GLP Not Published Syngenta File N° SAN837/5103	N	SYN
KCP 6.4.1/02	Gilsdorf. D.. Weissenburger. B.	1979	Effect of feeding Dicamba to dairy cattle (Residues in Liver. Kidney. Muscle. and Fat) Novartis Crop Protection AG. Basel. Switzerland Brian Christensen Companies. Inc.. Minnetonka. United States. Report No 379 GLP Not Published Syngenta File N° SAN837/5104	N	SYN
KCP	Hutchinson. C.	1984	Transfer of dicamba residues to tissues and eggs of laying hens	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.4.1/03			Novartis Crop Protection AG. Basel. Switzerland Wildlife International Ltd.. Easton. MD. United States. Report No 107-203 Not GLP Not Published Syngenta File N° SAN837/5392		
KCP 6.4.1/04	Cahill. W.P.. Johnson. L.R.	1984	Determination of Dicamba Residue in Laying Hen Tissues and Eggs After a 28 Day Feeding Study Novartis Crop Protection AG. Basel. Switzerland Velsicol Environmental Science. Chicago. United States. Report No 74 Not GLP Not Published Syngenta File N° SAN837/5106	N	SYN
KCP 6.5.1/01	Grout. S.J.	2003	Aqueous Hydrolysis at 90°. 100 & 120 °C Syngenta Crop Protection AG. Basel. Switzerland Syngenta - Jealott's Hill International. Bracknell. Berkshire. United Kingdom. Report No RJ3333B GLP Not Published Syngenta File N° SAN837/6087	N	SYN
KCP 6.6.1/01	Moore P.A.	1991	Confined accumulation study of dicamba on rotational crops after fall application Sandoz Agro Inc. Report No 18 GLP Not published Syngenta File No. SAN837/5297 Study not relevant for EU purposes	N	SYN
KCP 6.6.1/02	Moore P.A.	1989	Confined Accumulation Studies of Dicamba on Rotational Crops After Spring Application Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 16 Not GLP Not Published Syngenta File N° SAN837/5108	N	SYN
KCP	Pierotti. M.V.	1995	Confined Accumulation Studies of Dicamba on Rotational Crops	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.6.1/03			Novartis Crop Protection AG. Basel. Switzerland Sandoz Agro Inc.. Des Plaines. United States. Report No 22 GLP Not Published Syngenta File N° SAN837/5282		

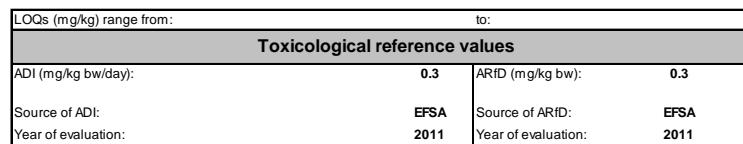
Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Dicamba

Not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



Supplementary results - chronic risk assessment

Details - acute risk assessment/adults

[illegible][illegible]

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

				No of diets exceeding the ADI : ---								Exposure resulting from	
	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)		
	MS Diet												
TMD/INWED/EDI calculation (based on average food consumption)	1%	NL toddler	3.52	1%	Maize/corn								
	0.2%	GEMS/Food G06	0.63	0.2%	Maize/corn		Grapefruits						
	0.2%	UK infant	0.51	0.2%	Maize/corn		Grapefruits						
	0.2%	RO general	0.48	0.2%	Maize/corn		Grapefruits						
	0.1%	GEMS/Food G10	0.33	0.1%	Maize/corn		Grapefruits						
	0.1%	GEMS/Food G15	0.32	0.1%	Maize/corn		Grapefruits						
	0.1%	PT general	0.24	0.1%	Maize/corn		Grapefruits						
	0.1%	GEMS/Food G08	0.22	0.1%	Maize/corn		Grapefruits						
	0.1%	FR child 3 15 yr	0.21	0.1%	Maize/corn		Grapefruits						
	0.1%	GEMS/Food G07	0.15	0.1%	Maize/corn		Grapefruits						
	0.0%	ES child	0.14	0.0%	Maize/corn		Grapefruits						
	0.0%	NL child	0.14	0.0%	Maize/corn		Grapefruits						
	0.0%	IE adult	0.11	0.0%	Maize/corn		Grapefruits						
	0.0%	DE child	0.08	0.0%	Maize/corn		Grapefruits						
	0.0%	GEMS/Food G11	0.06	0.0%	Maize/corn		Grapefruits						
	0.0%	NL general	0.05	0.0%	Maize/corn		Grapefruits						
	0.0%	FR toddler 2 3 yr	0.04	0.0%	Maize/corn		Grapefruits						
	0.0%	ES adult	0.04	0.0%	Maize/corn		Grapefruits						
	0.0%	DE women 14-50 yr	0.03	0.0%	Maize/corn		Grapefruits						
	0.0%	FR adult	0.03	0.0%	Maize/corn		Grapefruits						
	0.0%	DE general	0.03	0.0%	Maize/corn		Grapefruits						
	0.0%	IT toddler	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	FI 6 yr	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	FR infant	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	IT adult	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	FI 3 yr	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	UK toddler	0.01	0.0%	Maize/corn		Grapefruits						
	0.0%	UK vegetarian	0.00	0.0%	Maize/corn		Grapefruits						
	0.0%	LT adult	0.00	0.0%	Maize/corn		Grapefruits						
	0.0%	FI adult	0.00	0.0%	Maize/corn		Grapefruits						
0.0%	UK adult	0.00	0.0%	Maize/corn		Grapefruits							
0.0%	PL general	0.00	0.0%	Maize/corn		Grapefruits							
0.0%	IE child	0.00	0.0%	Maize/corn		Grapefruits							
0.0%	DK child	0.00	0.0%	Maize/corn		Grapefruits							
	DK adult				Grapefruits								
	DK adult				Grapefruits								

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of is unlikely to present a public health concern.

A 3.2 IESTI calculations - Raw commodities

Acute risk assessment /children					Acute risk assessment / adults / general population					
Details - acute risk assessment /children					Details - acute risk assessment/adults					
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.										
Show results for all crops										
Unprocessed commodities	Results for children				Results for adults					
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):					
	IESTI				IESTI					
	Highest % of ARfD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		
	1%	Maize/corn	0.5 / 0.5	3.4	0.4%	Maize/corn	0.5 / 0.5	1.1		
Expand/collapse list										
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)										
Processed commodities	Results for children				Results for adults					
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):					
	IESTI				IESTI					
	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		
	4%	Maize / oil	0.5 / 12.5	12	2%	Maize / oil	0.5 / 12.5	6.3		
	0.4%	Maize / processed (not spe	0.5 / 0.5	1.1	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		
	Expand/collapse list									

Appendix 4 Additional information provided by the applicant